IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	LIEBERMAN, DANIEL	DOCKET NO.:	3998P2652
SERIAL NO.:	10/646,903	EXAMINER:	MACNEILL, E.
FILED:	08/22/2003	ART UNIT:	3767
TITLE:	METHOD AND APPARATUS FOR IRRIGATION AND DRAINAGE OF THE BRAIN'S SUBDURAL SPACE USING A PERCUTANEOUS APPROACH		

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I hereby certify that on the 11th day of January, 2008, this correspondence is being filed electronically on EFS-Web.

/s/ Karen J. Sepura
Karen J. Sepura

APPELLANT'S REPLY BRIEF

Dear Sir:

This brief is submitted in support of the Appeal in the above-identified patent application and in reply to the Examiner's Answer mailed on November 14, 2007.

REPLY TO EXAMINER'S RESPONSE TO ARGUMENT

I. Rejection of Claim 11 as unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,605,036 to Wild

The Examiner contends that there is no structural difference between the drainage and irrigation tubes taught by Wild and the irrigation and drainage channels of applicant's Claim 11. Examiner's Answer, p. 5. Applicant respectfully submits that there is indeed a structural difference between the two. In this regard, applicant's tubes 561 support the irrigation channel 510; i.e., the tubes 561 hold the irrigation channel 510 in place inside the drainage channel 515. *See* Claim 11; Figure 6B. Wild does not do this – its irrigation channels 9 are not supported by such a structure. Although the Examiner now states that Wild's "bundle 3a and the lumen 10 are taken as the 'drainage channel'..." (Examiner's Answer, p. 5), this interpretation is contrary to the teachings of Wild, where the passive fluid escape channel 10, like other channels 5, 6, 7 and 9, is a distinct channel running through the shaft. *See* Wild, col. 11, lines 62-66 ("The two working channels 5, 6 lie below the level of the optical channel 7 and beneath them lies the passive escape fluid channel 10. Either side of the optical channel are the two small irrigation channels 9, providing clear fluid across the objective lens."). Thus, the bundle 3a is not part of the passive fluid escape channel 10, but instead is a "light-conveying optical fibre bundle 3a" that is part of a fibre optic light guide system 3. *See* Wild, col. 16, lines 40-44.

The Examiner also contends that Wild "is capable of performing the intended use [of draining a subdural hematoma] (as indicated at Col 1 line 53)...." Examiner's Answer, p. 5. However, Wild does not teach draining a subdural hematoma using its device. Rather, Wild's only reference to the treatment of subdural hematomas (which appears at col. 1, line 53) is with

respect to a discussion of prior art neurosurgery devices that stand in contrast to Wild's endoscopic device.

Accordingly, Applicant respectfully submits that the rejection of Claim 11 was in error.

II. Rejection of Claims 14 and 15-25 as unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,605,036 to Wild

a. Claims 14, 15, 18-22

Claim 14 is directed to a method for treating subdural hematomas. As discussed above, there is no discussion in Wild about using the Wild device for treating subdural hematomas. Wild's only reference to the treatment of subdural hematomas (appearing at col. 1, line 53) concerns prior art neurosurgery devices that are different from Wild's endoscopic device. More specifically, Wild states of U.S. Patent No. 2,038,394 to Wappler (Wild, col. 1, line 33) and British Patent Application No. 2004749 (*id.* at col. 1, line 36) that "[s]uch unifunctional instrument assemblies have found use in neurosurgery and other relatively complex procedures, including aspiration of intracerebral hematomas, drainage of chronic subdural hematomas, the fenestration of arachnoid and other cysts, third ventriculostomy, choroids plexus fulguration and spinal disc exenteration." Wild, col. 1, lines 50-55. In this *de minimis* discussion of subdural hematomas, Wild merely mentions prior art devices and various procedures in which they have found use. Wild does *not* teach the use of the Wild device in treating subdural hematomas.

Further, although the Examiner notes that Wild's "device may be rigid or flexible" (Examiner's Answer, p. 6), it is Wild's "optical viewing means" – namely, the "endoscopic telescope" – that may be rigid or flexible. Wild, col. 6, lines 11-13. Wild's endoscope shaft 4, which receives the endoscope, is rigid. Wild, col. 12, lines 52-54.

Finally, the Examiner contends that Wild's use of irrigation fluid meets Applicant's limitation of "irrigating said subdural space." Examiner's Answer, p. 6. However, nowhere in Wild is it taught to irrigate a subdural space in the manner claimed by Applicant. In this regard, Wild's "[i]rrigation fluid is delivered across the optical bundle as described above, so as to provide a clear view at all times." Wild, col. 13, lines 8-10. Further, although Wild's passive fluid escape channel provides gravity drainage and collection of fluids (*Id.* at col. 7, lines 48-50), nowhere does Wild discuss using that device for draining a subdural hematoma. Rather, Wild specifies that the passive fluid escape channel "allow[s] drainage of fluid and debris from out of the operating zone." *Id.* at lines 47-48.

Accordingly, Applicant respectfully submits that the rejection of Claim 14, as well as Claims 15 and 18-22 (which depend from Claim 14), was in error.

b. Claims 16-17

Applicant incorporates herein by reference the arguments regarding Claim 14 in Section II.a., above. In addition, in contrast to Applicant's invention, Wild teaches a surgical instrument for use in endoscopic surgery, and not the non-visual treatment of subdural hematomas. Although the Examiner notes that the endoscopic camera in Wild "is readily removable from the device," (Examiner's Answer, p. 6), Wild does not teach using the device without a camera. In this regard, Wild states that "[t]he telescope 2 is interchangeable in its channel 7 (the so-called "optical channel") with a range of alternative telescopes (not shown) selected from generally available endoscope telescope systems (e.g. rigid or flexible, stereoscopic or monoscopic, narrow or wide angle etc)." Wild, col. 11, lines 18-22.

Accordingly, Applicant respectfully submits that the rejection of Claims 16 and 17 (which depends from Claim 16) was in error.

c. Claim 23

Applicant incorporates herein by reference the arguments regarding Claim 14 in Section II.a., above. In addition, Claim 23 provides for a tuohy needle, which is not present in the Wild reference. A tuohy needle, which is well-known in the art, has a curved tip (*see* Specification, p. 10, lines 23-24; Fig. 2). Conversely, the outer tube 25 of Wild – which "constitut[es] an outer sheath part of the shaft 21 of the instrument" (Wild, col. 14, lines 5-7) – is not a tuohy needle and lacks a curved tip. *See* Wild, Fig. 13. With respect to Figure 13 of Wild, the operative inner part 26 projects from the outer tube 25 at an angle due to its rigidity. Thus, where the operative inner part 26 lacks inherent rigidity, Wild provides for a different embodiment: "[w]here the operative inner part of the shaft of the instrument (e.g. the laser fibre of FIGS. 6 and 7) has no inherent rigidity and cannot maintain the angulation, a firm but bendable sheath or gutter (e.g. of elastic metal) 29 may support the operative inner part of the shaft of the instrument in the desired configuration." Wild, col. 14, lines 16-21.

Accordingly, Applicant respectfully submits that the rejection of Claim 23 was in error.

d. Claim 24

Applicant incorporates herein by reference the arguments regarding Claims 14 and 23 in Sections II.a. and II.c., above. In addition, Claim 24 provides for a guide wire, which is not present in the Wild reference. Wild does not teach inserting a guide wire into a tuohy needle, nor does Wild teach advancing a dual lumen catheter along a guide wire, as Claim 24 requires.

While the Examiner contends that Wild's push-pull wires meet Applicant's claim limitations of advancing the catheter along the guide wire into the subdural space, Wild's push-pull wires direct the deflection of only a short rigid section of an endoscope, and the endoscope is not advanced along the push-pull wires. As Wild discloses, "[s]uch a steerable endoscope typically incorporates three push-pull wires attached to a *short distal rigid section* containing the field collecting lens system, the wires being used to *deflect the rigid section* in any desired direction." Wild, col. 6, lines 40-44 (emphasis added). Thus, Applicant's method, which positions the dual lumen catheter 310 in the subdural space 125 by advancing it along the guide wire 207, is distinctly different. *See* Specification, p. 11, lines 2-4; Fig. 3.

Accordingly, Applicant respectfully submits that the rejection of Claim 24 was in error.

e. Claim 25

Applicant incorporates herein by reference the arguments regarding Claim 14 in Section II.a., above. In addition, Claim 25 provides for a stylette, which is not present in the Wild reference. Wild does not teach inserting a stylette into a dual lumen catheter in order to give the dual lumen catheter rigidity, as Claim 25 requires. While the Examiner contends that Wild's rigid telescope 2 meets Applicant's claim in that it "is removable and gives the catheter rigidity," Applicant respectfully submits that this is incorrect. In this regard, Wild's "rigid telescope 2 is inserted through the optical channel 7 in the endoscope shaft 4...." Wild, col. 11, lines 46-47. The endoscope shaft 4 itself is "rigid." *Id.* at col. 12, line 53. Thus, Wild's rigid telescope 2 does not provide temporary rigidity for a dual lumen catheter, as claimed by Applicant.

Accordingly, Applicant respectfully submits that the rejection of Claim 25 was in error.

III. Rejection of Claims 26-27 as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,605,036 to Wild in view of Dardik et al. (Journal of Vascular Surgery)

Applicant incorporates herein by reference the arguments regarding Claim 14 in Section II.a., above. In addition, Applicant submits that the methods of Claims 26-27 are neither taught nor reasonably suggested by the references on which the Examiner relies. With respect to the Dardik reference, while the Examiner contends that "the drains were used to treat subdural hematomas" (Examiner's Answer, p. 7), Applicant respectfully submits that this is incorrect. The drains in Dardik were used to remove *cerebrospinal fluid* ("CSF") from patients, not to treat subdural hematomas. Thus, Dardik notes that "*CSF drainage* began in the operating room and continued for 3 days after surgery." Dardik, pp. 47-48 (emphasis added). *See also id.* at p. 48 ("Drains were set to allow *drainage of CSF*.... All drains were removed on the third postoperative day.") (emphasis added). Although subdural hematomas are discussed in Dardik, they are not discussed in the context of treatment in the manner taught by Applicant. Instead, in Dardik, the development of subdural hematomas is discussed as being a possible complication in patients following thoracoabdominal aortic aneurysm repair ("TAAA repair"), where cerebrospinal fluid drainage was used adjunct to the TAAA repair. *See* Dardik, Abstract.

Accordingly, Applicant respectfully submits that the rejection of Claims 26-27 was in error.

CONCLUSION

For the reasons stated above, as well as those articulated in Applicant's Appeal Brief, Applicant respectfully submits that the final rejection of Claims 11 and 14-27 was in error, and

that these claims should be allowed. Accordingly, Applicant respectfully urges the Board to reverse the Examiner's final rejection of these claims.

No additional fee or extension of time is believed to be required; however, in the event that an additional fee or extension of time is required, please charge that fee or extension of time requested to our Deposit Account No. 23-0830.

Respectfully submitted,

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